



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2012-0780; FRL-9368-5]

### **MON 87410 and MON 87411 Pesticide-Incorporated Protectant Corn Events: Pesticide Experimental Use Permit; Receipt of Application; Comment Request**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces EPA's receipt of an application 524-EUP-RNU from Monsanto Company requesting an experimental use permit (EUP) for the plant-incorporated protectants (PIPs) corn events with a double stranded RNA (dsRNA) transcript comprising a Dv49 inverted repeat sequence derived from *Diabrotica virgifera*, and the genetic material necessary for its production (vector PV-ZMIR10871). These events are proposed for experimental use in combination with single and combined traits against lepidoptera and corn rootworm (CRW). The Agency has determined that the permit may be of regional and national significance. Therefore, because of the potential significance, EPA is seeking comments on this application.

**DATES:** Comments must be received on or before *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2012-0780, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

*<http://www.epa.gov/dockets/contacts.htm>.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *<http://www.epa.gov/dockets>*.

**FOR FURTHER INFORMATION CONTACT:** Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; email address: *[bacchus.shanaz@epa.gov](mailto:bacchus.shanaz@epa.gov)*.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action.

#### *B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI*. Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or

CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:
  - i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
  - ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
  - iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
  - iv. Describe any assumptions and provide any technical information and/or data that you used.
  - v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
  - vi. Provide specific examples to illustrate your concerns and suggest alternatives.
  - vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
  - viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

## **II. What Action is the Agency Taking?**

Under section 5 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136c, EPA can allow manufacturers to field test pesticides under development. Manufacturers are required to obtain an EUP before testing new pesticides or new uses of pesticides if they conduct experimental field tests on 10 acres or more of land or one acre or more of water.

In accordance with 40 CFR 172.11(a), the Agency has determined that the following EUP application may be of regional and national significance, and therefore is seeking public comment on the EUP application:

*Submitter:* Monsanto Company, (524-EUP-RNU).

*Pesticide Chemical:* Double stranded RNA (dsRNA) transcript comprising a Dv49 inverted repeat sequence derived from *Diabrotica virgifera*, and the genetic material necessary for its production (vector PV-ZMIR10871).

*Summary of Request:* Monsanto is requesting a EUP for two years to test new PIP technology for control of corn rootworm (CRW), a major pest of corn in the United States (U.S.). Corn Events MON 87410 and 87411 express a double stranded RNA (dsRNA) transcript suppression cassette with an inverted repeat sequence, Dv49, obtained from *Diabrotica virgifera*. When PIP-produced Dv49 dsRNA is consumed by the pest, it down regulates the targeted pest's *Snf7* gene, resulting in pest mortality.

As described in the application documents for 524-EUP-RNU in this docket, the PIP events comprising the single and combined trait products in this request include other registered PIP *Bacillus thuringiensis* (*Bt*) proteins and either of the two new corn events MON 87410 and 87411. The *Bt* proteins to be used in the single or combination traits in the proposed EUP include Cry1A.105, Cry2Ab2, Cry IF, Vip3Aa20, Cry3Bb1, Cry34Abl/Cry35Abl and eCry3.1Ab. The environmental and human health safety of these proteins has been demonstrated, and they are exempted from the requirement of a tolerance (40 CFR 174.501, 174.502, 174.506, 174.518, 174.519, 174.520, 174.528, 174.532). A permanent tolerance exemption has been established for nucleic acids including the dsRNA that is part of the PIPs (40 CFR 174.507). Other marker proteins PAT, CP4 EPSPS, and PMI are also exempt from the requirement of a tolerance (40 CFR 174.522, 174.523, 174.527).

The tests will be conducted in the U.S. territory of Puerto Rico and in the U.S. in twenty two (22) states as follows: Arkansas (AR), California (CA), Colorado (CO), Georgia (GA), Hawaii (HI), Idaho (ID), Illinois (IL), Indiana (IN), Iowa (IA), Kansas (KS), Michigan (MI), Minnesota (MN), Mississippi (MS), Missouri (MO), Nebraska

(NE), North Carolina (NC), Ohio (OH), Pennsylvania (PA), South Carolina (SC), South Dakota (SD), Tennessee (TN), Wisconsin (WI).

The two protocols in the EUP include: (1) seed development and increase for future testing including nursery observations of traits in various genetic backgrounds; and (2) product characterization work including phenotypic and agronomic observations, efficacy, yield benefit evaluations and regulatory data generation.

A copy of the application and any information submitted is available for public review in the docket established for this EUP application.

Following the review of the application and any comments and data received in response to this solicitation, EPA will decide whether to issue or deny the EUP request, and if issued, the conditions under which it is to be conducted. Any issuance of an EUP will be announced in the **Federal Register**.

**List of Subjects**

Environmental protection, Experimental use permits.

Dated: November 8, 2012,

Keith Matthews,

*Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*